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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/552,289

10/04/2005

Youichi Yamaguchi

81844.0045

2004.

26021 7590 06/01/2007
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EXAMINER

VU, QUYNH-NHU HOANG

ART UNIT

PAPER NUMBER

3763

MAIL DATE

DELIVERY MODE

06/01/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/552,289

Applicant(s)

YAMAGUCHI ET AL.

Examiner

Quynh-Nhu H. Vu

Art Unit

3763

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 04 October 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-17 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-17 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>10/04/05 & 05/30/06</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Specification

The following guidelines illustrate the preferred layout for the specification of a utility application. These guidelines are suggested for the applicant's use.

Arrangement of the Specification

As provided in 37 CFR 1.77(b), the specification of a utility application should include the following sections in order. Each of the lettered items should appear in upper case, without underlining or bold type, as a section heading. If no text follows the section heading, the phrase "Not Applicable" should follow the section heading:

- (a) TITLE OF THE INVENTION.
- (b) CROSS-REFERENCE TO RELATED APPLICATIONS.
- (c) STATEMENT REGARDING FEDERALLY SPONSORED RESEARCH OR DEVELOPMENT.
- (d) THE NAMES OF THE PARTIES TO A JOINT RESEARCH AGREEMENT.
- (e) INCORPORATION-BY-REFERENCE OF MATERIAL SUBMITTED ON A COMPACT DISC.
- (f) BACKGROUND OF THE INVENTION.
 - (1) Field of the Invention.
 - (2) Description of Related Art including information disclosed under 37 CFR 1.97 and 1.98.
- (g) BRIEF SUMMARY OF THE INVENTION.
- (h) BRIEF DESCRIPTION OF THE SEVERAL VIEWS OF THE DRAWING(S).
- (i) DETAILED DESCRIPTION OF THE INVENTION.
- (j) CLAIM OR CLAIMS (commencing on a separate sheet).
- (k) ABSTRACT OF THE DISCLOSURE (commencing on a separate sheet).
- (l) SEQUENCE LISTING (See MPEP § 2424 and 37 CFR 1.821-1.825. A "Sequence Listing" is required on paper if the application discloses a nucleotide or amino acid sequence as defined in 37 CFR 1.821(a) and if the required "Sequence Listing" is not submitted as an electronic document on compact disc).

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

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A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-7, 13 and 16-17 are rejected under 35 U.S.C. 102(b) as being anticipated by Montano, Jr. (US 5,041,125).

Montano discloses in Figs. 1-8 a medical balloon catheter 10 comprising a balloon 18 having a groove 24 and a projection helically provide on the balloon relative to the longitudinal axis of the balloon.

Regarding claim 2, the groove and the projection are helically provided on at least one balloon taper relative to the longitudinal axis of the balloon.

Regarding claim 3, the groove 24 provided on a balloon taper relative to the longitudinal axis of the balloon are continuously provided at an angel from 10° to 45° when viewed from the distal end, the angle being defined by a centerline connecting the center and a starting point and another line connecting the center and an ending point (col. 2, lines 1-10).

Regarding claims 4-5, a plurality of grooves 24 are provided on a distal balloon taper relative to the longitudinal axis of the balloon, said the groove being extending from the distal end to the proximal side.

Regarding claim 6, the number of the grooves provided on a balloon taper relative to the longitudinal axis of the balloon is from three to eight (col. 1, lines 66 or claim 8).

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Regarding claim 7, the width of the groove provided on a balloon taper relative to the longitudinal axis of the balloon varies in the direction of the longitudinal axis of the balloon.

Regarding claim 13, a method of producing a balloon catheter comprising forming the balloon with a mold (col. 4, lines 5-18).

Regarding claims 16-17, the scope of the claims is similar to that of claim 4 except it is drafted in a method format instead of apparatus format. The claims are therefore rejected for the same reason as set forth above.

Claims 1- 5, 8-11 and 13 are rejected under 35 U.S.C. 102(b) as being anticipated by Fagan et al. (hereinafter 'Fagan') (US 5,545,132).

Fagan discloses, in Figs. 1-7B, a medical balloon catheter 10 comprising a balloon 12 having a helical groove 16 provided on at least one balloon taper 18, 20 and on the balloon relative to the longitudinal axis of the balloon (claims 1-2).

Regarding claim 3, the groove 16 provided on a balloon taper relative to the longitudinal axis of the balloon are continuously provided at an angle of 45° in the range of 15° to 180° when viewed from the distal end, the angle being defined by a centerline connecting to the center and a starting point and another line connecting the center and an ending point.

Regarding claim 4, the groove extending from the distal end to the proximal side.

Regarding claim 5, a plurality of grooves provided on a balloon taper 18, 20 (Fig. 3).

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Regarding claims 8-9, a width of the groove is 0.005 inches = 127 μm (col. 6, lines 25-26) in the range of 1 to 1000 μm .

Regarding claims 10-11, a depth of the groove is 1mm (col. 6, lines 13-15).

Regarding claim 13, forming the balloon with a mold (col. 4, lines 40-41).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 8-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Montano, Jr. (US 5,041,125).

Montano discloses the claimed invention except for the width of groove provided on a balloon taper relative to the longitudinal axis of the balloon is 1 μm or more (claim 8), 10 μm to 1000 μm (claim 9); a depth of the groove is 0.001 mm or 3.0 mm (claims 10-11), a length of the groove is 0.1mm to 4.0 mm (claims 11-12). It would have been obvious to one ordinary skill in the art at the time the invention was made to the width, the depth and length of groove with values above, since it has been held that discovering an optimum value of a result effective variable involves only routine skill in the art.

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Claims 14-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Montano, Jr. (US 5,041,125)/ Fagan et al. (US 5,545,132) in view of Forman (US 5,733,301).

Montano, Jr. or Fagan et al. discloses the claimed invention (see above) except for a method for producing a balloon catheter comprising: applying thermal energy or irradiating with a laser to form a groove provided on the balloon.

Forman discloses, in Figs. 5-7, a method of forming a groove or unwanted material removed (indicated at 58) by using laser beam 48 (col. 6, line 60-col. 7, line 18 and lines 32-35). Forman discloses that heat is applied to the ejected material, thus the Examiner is considering that thermal energy is applied. (col. 7, line 66-col. 8, line 18).

It would have been obvious to one ordinary skill in the art at the time the invention was made to apply the method of thermal energy or laser, as taught by Forman, for removing unwanted material or for forming a groove as an alternative method of making the balloon by molding. Additionally, the method of using laser or thermal energy to form a groove is well known in the art.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Quynh-Nhu H. Vu whose telephone number is 571-272-3228. The examiner can normally be reached on 6:00 am to 3:00 pm.

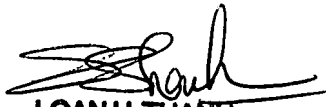
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nicholas Lucchesi can be reached on 571-272-4977. The fax phone

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number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

QNV



LOAN H. THANH
PRIMARY EXAMINER